

PTO/SB/088 (04-03)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/621,027
		Filing Date	July 16, 2003
		First Named Inventor	Nai-Kong Cheung
		Art Unit	1623
		Examiner Name	Jason H. Johnsen
Sheet 1	of 1	Attorney Docket Number	639-B-PCT-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
Eso	1	Search Report prepared by the Norwegian Patent Office, dated May 4, 2005	
Eso	2	Hong et al., "Mechanism by Which Orally Administered $\beta$ -1,3-Glucans Enhance the Tumoricidal Activity of Antitumor Monoclonal Antibodies in Murine Tumor Models", Journal of Immunology, Vol. 173, No. 5, Pages 797-806 (2004)	
Eso	3	Ostroff et al., "Immune-Enhancing Effects of Oral Yeast $\beta$ 1,3/1,6 Glucans", American Chemical Society, Vol. 225, No. 1-2, pp. AGFD 8 (2003)	
Eso	4	Allendorf et al., "Macrophages shuttle orally administered $\beta$ -glucan to potentiate the CR3-dependent tumoricidal effects of monoclonal antibodies in mouse tumor models", FASEB Journal, Vol. 17, No. 7, Page C128 (2004)	
Eso	5	Papila et al., "The Effect of oral $\beta$ -glucan in addition to systemic chemotherapy on the leukocyte values with oral mucositis in the patients with head-neck tumors", International Review of Allergology & Clinical Immunology, Vol 10, No. 2, Pages 59-61 (2004)	

Examiner Signature	<i>Eric S. John</i>	Date Considered	12/19/06
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		Examiner Name	Jason H. Johnson
Sheet <u>1</u>	of <u>1</u>	Attorney Docket Number 639-B-PCT-US	

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ESO	11	Kidd, P., "The Use of Mushroom Glucans and Proteoglycans in Cancer Treatment", Alternative Medicine Review, Vol. 5, No. 1, Pages 4-27 (2000)	
	12	Hanaue, H. et al, "Effects of Oral Lentinan on T-Cell Subsets in Periphe Venous Blood", Clinical Therapeutics, Vol. 5 (1989)	
	13	Suzuki, M. et al, "Antitumor and Immunological Activity of Lentinan in Comparison with LPS", International Society of Pharmacology, Ltd., Pages 463-468 (1994)	
	14	Cheung, N.; Modak, S.; "Oral (1-3), (1-4)-B-D-Glucan Synergizes with Antiganglioside GD2 Monoclonal Antibody 3F8 in the Therapy of Neuroblastoma", Clinical Cancer Research, Vol. 8, Pages 1217-1223 (2002)	
	15	Chihara, G. et al., "Antitumor and Metastasis-Inhibitory Activities of Lentinan as an Immunomodulator: An Overview", Cancer Detection and Prevention Supplement, Vol. 1, Pages 423-443 (1987)	
✓	16	Mayer, L.; Shao, L., "Therapeutic Potential of Oral Tolerance", Nature Reviews Immunology, Vol. 4, Pages 407-419 (2004)	

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Examiner Name	Jason H. Johnsen
Attorney Docket Number	639-B-PCT-US

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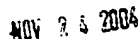
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ESD	1	PCT International Search Report for Sloan-Kettering Institute for Cancer Research, Int'l Application No. PCT/US04/23099, Filed July 16, 2004, Dated February 28, 2005	
	2	Babineau, T. et al., "Randomized Phase I/II Trial of a Macrophage-Specific Immunomodulator (PGG-Glucan) in High-Risk Surgical Patients", Annals of Surgery, Vol. 220, No. 5, Pages 601-609 (1994)	
	3	Babineau, T. et al., "A Phase II Multicenter, Double-blind, Randomized, Placebo-Controlled Study of Three Dosages of an Immunomodulator (PGG-Glucan) in High Risk Surgical Patients", Arch Surg, Vol. 129, Pages 1204-1210 (1994)	
	4	Arturson, G.; Wallenius, G., "The Renal Clearance of Dextran of Different Molecular Sizes in Normal Humans", Scandina J Clin & Lab Investigation, Vol. 1, Pages 81-86 (1964)	
	5	Dellinger, E., et al., "Effect of PGG-glucan on the Rate of Serious Postoperative Infection or Death Observed After High-Risk Gastrointestinal Operations", Arch Surg, Vol 134, Pages 977-983 (1999)	
	6	Arturson, G. et al., "Intravascular Persistence and Renal Clearance of Dextran of Different Molecular Sizes in Normal Children", Arch Dis Childh., Vol. 41, Pages 168-172 (1966)	
	7	Sortwell, R. et al., "Chronic Intravenous Administration of Lentinan to the Rhesus Monkey", Toxicology Letters, Vol. 9, Pages 81-85 (1981)	
	8	Shimazu, H. et al., "Intravenous chronic toxicity of lentinan in rats: 6-month treatment and 3-month recovery", National Library of Medicine (PubMed), J Toxicol Sci, Pages 33-57 (1980)	
	9	Mehvar, R., "Recent Trends in the Use of Polysaccharides for Improved Delivery of Therapeutic Agents: Pharmacokinetic and Pharmacodynamic Perspectives", Current Pharmaceutical Biotechnology, Vol. 4, Pages 283-302 (2003)	
✓	10	Hanaue, H. et al., "Basic Studies on Oral Administration of Lentinan (I)", J. Jpn. Cancer Ther., Vol. 8, Pages 1566-1571 (1989)	

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Sheet 1

of 2

**Complete if Known**

Application Number	10/621.027
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<b>Filing Date</b>	July 16, 2003
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First Named Inventor	Nai-Kong Chueng
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**Art Unit**

Examiner Name

Attorney Docket Number	639-B-PCT-US
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## U. S. PATENT DOCUMENTS

[illegible]

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		Filing Date	July 16, 2003		
		First Named Inventor	Nai-Kong CHEUNG		
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Sheet	2	of	2	Attorney Docket Number	639-B-PCT-US

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ESO	3	Ross, et al. Therapeutic intervention with complement and beta-glucan in cancer, Immunopharmacology 42(1999), 61-74	
ESO	4	Vetvicka, et al. Pilot Study: Orally-administered Yeast beta-(1,3)-glucan prophylactically protect against anthrax infection and cancer in mice. Journ Ameri Nutraceutical Assoc, Vol. 5:2, April 22, 2002	
ESO	5	Cheung, N.K. Orally administered beta-glucans enhance anti-tumor effects of monoclonal antibodies. Cancer Immunother. 2002 Nov; 51(10):557-64	
ESO	6	Suzuki, et al. Effect of orally administered beta-glucan on macrophage function in mice. Int. J. Immunopharmacology 12:6, 675-684, 1990	

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		Country Code <sup>4</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
E50	1	WO 2004/014320 A2	02/19/2004	Ostroff, et al.		
	2	WO 2004/014320 A3	02/19/2004	Ostroff, et al.		
	3	WO 2004/021994 A2	03/18/2004	Ostroff, et al.		
	4	WO 2004/021994 A3	03/18/2004	Ostroff, et al.		

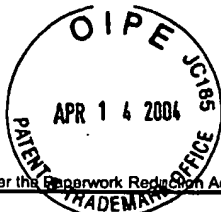
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ESO	1	S. Tsukagoshi, Y. Hashimoto, G. Fujii, H. Kobayashi, K. Nomoto, and K. Orita, Krestin (PSK). Cancer Treat. Rev. 11:131-155, 1984.	
	2	H. Nanba, H. and H. Kuroda, Antitumor mechanisms of orally administered shiitake fruit bodies. Chem. Pharm. Bull. (Tokyo) 35:2459-2464, 1987.	
	3	H. Nanba, H., K. Mori, T. Toyomasu, and H. Kuroda, Antitumor action of shiitake (Lentinus edodes) fruit bodies orally administered to mice. Chem. Pharm. Bull. (Tokyo) 35:2453-2458, 1987.	
	4	I. Hishida, H. Nanba, and H. Kuroda, Antitumor activity exhibited by orally administered extract from fruit body of Grifola frondosa (maitake). Chem. Pharm. Bull. (Tokyo) 36:1819-1827, 1988.	
	5	H. Nanba and H. Kuroda, Potentiation of host-mediated antitumor activity by orally administered mushroom (Agaricus bispora) fruit bodies. Chem. Pharm. Bull. (Tokyo) 36:1437-1444, 1988.	
	6	T. Ohmori, K. Tamura, A. Wakaiki, G. Kawanishi, S. Tsuru, T. Yadomae, and K. Nomoto, Dissociation of a glucan fraction (CO-1) from protein-bound polysaccharide of Cordyceps phloglossoides and analysis of its antitumor effect. Chem. Pharm. Bull. (Tokyo) 36:4512-4518, 1988.	
	7	H. Hanaue, Y. Tokuda, T. Machimura, A. Kamijoh, Y. Kondo, K. Ogoshi, H. Makuuchi, H. Nakasaki, T. Tajima, and T. Mitomi, Effects of oral lentinan on T-cell subsets in peripheral venous blood. Clin. Ther. 11:614-622, 1989.	
	8	I. Suzuki, K. Hashimoto, N. Ohno, H. Tanaka, and T. Yadomae, Immunomodulation by orally administered $\beta$ -glucan in mice. Int. J. Immunopharmacol. 11:761-769, 1989.	
	9	I. Suzuki, T. Sakurai, K. Hashimoto, S. Oikawa, A. Masuda, M. Ohsawa, and T. Yadomae, Inhibition of experimental pulmonary metastasis of Lewis lung carcinoma by orally administered $\beta$ -glucan in mice. Chem. Pharm. Bull. (Tokyo) 39:1606-1608, 1991.	
	10	T. Sakurai, K. Hashimoto, I. Suzuki, N. Ohno, S. Oikawa, A. Masuda, and T. Yadomae, Enhancement of murine alveolar macrophage functions by orally administered $\beta$ -glucan. Int. J. Immunopharmacol. 14:821-830, 1992.	

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	12	H. Hotta, K. Hagiwara, K. Tabata, W. Ito, and M. Homma, Augmentation of protective immune responses against Sendai virus infection by fungal polysaccharide schizophyllan. Int. J. Immunopharmacol. 15:55-60, 1993.	
	13	H. Morinaga, K. Tazawa, H. Tagoh, A. Muraguchi, and M. Fujimaki, An in vivo study of hepatic and splenic interleukin-1 $\beta$ mRNA expression following oral PSK or LEM administration. Gann 85:1298-1303, 1984.	
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	15	H. Nanba, Activity of maitake D-fraction to inhibit carcinogenesis and metastasis. Ann. N. Y. Acad. Sci. 768:243-245, 1995.	
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